

PSJ3

Exhibit 480

From: Gray, John <jgray@hdmanet.org>
Sent: Friday, May 04, 2012 7:26 PM
To: Kelly, Patrick
Subject: FW: NACDS Issue Paper
Attachments: NACDS Drug Diversion - PDUFA1.doc

Call me about this....just spoke with Connie. John

From: Woodburn, Connie [<mailto:Connie.Woodburn@cardinalhealth.com>]
Sent: Friday, May 04, 2012 3:20 PM
To: Gray, John; Kelly, Patrick
Subject: NACDS Issue Paper

Here it is. Thanks so much for your time.

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NATIONAL ASSOCIATION OF
CHAIN DRUG STORES

Drug Shortages and Drug Diversion

NACDS and the chain pharmacy industry are committed to partnering with law enforcement agencies, policymakers, and others to work on viable strategies to prevent prescription drug diversion and abuse. Our members are engaged daily in activities with the goal of preventing drug diversion and abuse.

Presently, the federal Drug Enforcement Administration (DEA) has federal jurisdiction over prescription drugs that are subject to diversion and abuse ("controlled substances") and the activities of healthcare providers with respect to controlled substances, including anti-diversion activities. For healthcare providers, DEA issues registrations and implements regulations. For prescribers, this registration allows them to provide care to patients in the form of ordering prescriptions for controlled substances. For pharmacies, the registration allows them to order, store, and dispense controlled substance medications to legitimate patients.

DEA has implemented regulations to minimize the diversion of controlled substances. Our members have developed extensive policies and procedures to comply with DEA's regulatory regime, and similar requirements from state agencies, such as boards of pharmacy and narcotic drug agencies. A complex regulatory and policy matrix of checks and balances protects Americans.

However, over the past few years, DEA actions have closed prescription drug distribution centers and pharmacies, potentially leading to legitimate patients not being able to receive their medications. Recent DEA actions against pharmacies may lead to pharmacies having to turn away legitimate patients. DEA's controlled substance production quotas may be leading to drug shortages that leave patients without their medication. DEA's goal in setting the production quotas and taking these other actions is to prevent prescription drug diversion.

Within existing draft PDUFA legislation is language to address the ongoing problem of prescription drug shortages, including requirements for DEA to work with FDA on addressing this problem. However, there is no language regarding prescription drug diversion/abuse. NACDS seeks similar language to require DEA to work with FDA on prescription drug diversion/abuse issues to ensure that all DEA's diversion-related actions take into consideration the impact those actions would have on patient care and access to controlled substance medications. Requiring DEA to work with FDA only on drug shortage issues will address some of the ongoing problems affecting patient care and medication access. Requiring DEA to work with FDA on all drug diversion/abuse issues will ensure that patient care concerns are considered when DEA takes anti-diversion action affecting prescription medications and healthcare providers.

While an appropriately policy must empower DEA to act aggressively against individuals and companies actually engaging in diversion or having few if any meaningful controls to prevent diversion, diversion control actions must be balanced against the needs of healthcare providers to provide care to legitimate patients. We must ensure that legitimate patients receive critical medicines without interruption.

May 1, 2012

Suggested Legislative Amendments to House E&C Draft

SEC. 906. ANNUAL REPORT ON DRUG SHORTAGES AND DRUG DIVERSION/ABUSE.

Not later than 18 months after the date of the enactment of this Act, and annually thereafter, the Secretary of Health and Human Services shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on drug shortages **and drug diversion/abuse** that ...

(3) describes the coordination between the Food and Drug Administration and the Drug Enforcement Administration on efforts to prevent or alleviate drug shortages, **and to prevent or reduce drug diversion and abuse to ensure that legitimate patients continue to have access to medications**;

SEC. 907. ATTORNEY GENERAL REPORT ON DRUG SHORTAGES AND DRUG DIVERSION/ABUSE.

Not later than 6 months after the date of the enactment of this Act, and annually thereafter, the Attorney General shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on the Judiciary of the Senate a report on drug shortages **and drug diversion/abuse** that ...

(2) describes the coordination between the Drug Enforcement Administration and Food and Drug Administration on efforts to prevent or alleviate drug shortages, **and to prevent or reduce drug diversion and abuse to ensure that legitimate patients continue to have access to medications**;